

MAY 1 8 2000

Attachment V

K 994225

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the SLP™ 2000 Diode Array Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Palomar Medical Technologies, Inc.

Address: 82 Cambridge St.
Burlington, MA 01803

Contact Person: Marcy Moore

Telephone: 919-363-2432

Preparation Date: November 15, 1999

Device Trade Name: Palomar SLP™ 2000

Common Name: Super Long Pulse Diode Laser

Classification Name: Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810).
Product Code: GEX
Panel: 79

Legally-Marketed Predicate Device: LightSheer Diode Array Laser
Star Medical Technologies, Inc.
K973324

System Description: The SLP™ 2000 delivers infrared laser light with a wavelength of 810 nm, a selectable pulse duration of 50 – 1000 ms, and a selectable pulse energy of .5-100 J. The corresponding fluence delivered through a 10 mm handpiece tip. The laser pulses are generated at a maximum pulse repetition frequency of 5 Hz by diodes located in the laser unit.

The complete system consists of a laser unit, chiller, a footswitch, and a handpiece connected to the laser unit with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a light pulse is delivered when the footswitch is depressed. The handpiece tip is water-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the user interface panel on top of the laser unit, which provides an interface to the system computer.

Intended Use of the Device:

The SLP™ 2000 Diode Laser System is indicated to remove hair in Dermatology and Plastic Surgery procedures. It is also intended for Photocoagulation of dermatological vascular lesions, including port wine stains, telangiectasia, angioma, spider nevi, and other benign vascular lesions.

Performance Data:

The differences in the specifications of the SLP™ 2000 laser and the predicate device do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the SLP™ 2000 Diode Array Laser System is substantially equivalent to the legally-marketed claimed predicate device, i.e., the LightSheer™ for hair removal.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Palomar Medical Technologies, Inc.
c/o Ms. Marcy Moore
Manager of Clinical Studies
131 Keleket Lane
Gary, North Carolina 27511

Re: K994225
Trade Name: Palomar SLP™ 1000
Regulatory Class: II
Product Code: GEX
Dated: March 27, 2000
Received: March 29, 2000

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K994225

Device Name: Palomar SLPTM 1000

Indications for Use:

The Palomar Super Long Pulse, SLPTM 1000, diode laser system is indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. Soft tissue which may be encountered in surgical procedures include skin, subcutaneous tissue, striated and smooth muscle, mucus membrane, lymph vessels and nodes, organs and glands, and specifically for the following indications.

Dermatology and Plastic Surgery for:

Hair Removal in Skin Types I-VI

Photocoagulation of dermatological vascular lesions, including port wine stains, telangiectasia, angioma, spider nevi, and other benign vascular lesions.

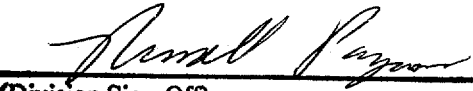
Photothermolysis of blood vessels
(treatment of facial and leg veins)

Removal of pigmented lesions

Photothermolysis

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K994225

Prescription Use ☒
(per 21 CFR 801.109)

OR

Over-the-Counter Use